4. PROGRAM REGULATIONS

4. PROGRAM REGULATIONS (cont.)

405.401: Introduction

All community health centers participating in MassHealth must comply with the regulations governing MassHealth, including but not limited to 130 CMR 405.000 and 130 CMR 450.000.

405.402: Definitions

The following terms used in 130 CMR 405.000 have the meanings given in 130 CMR 405.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 405.000 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 405.000 and in 130 CMR 450.000.

340B Covered Entities – facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

340B Drug-Pricing Program – a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992, permitting certain grantees of federal agencies access to reduced cost drugs for their patients.

Family Practitioner — a licensed physician who is board-eligible or board-certified in family practice. A family practitioner provides continuous, accessible medical care with emphasis on the family unit that combines appreciation of both the biomedical and psychosocial dimensions of illness. The family practitioner assumes responsibility for and provides most of the member's health care, and coordinates the member's total health needs.

Freestanding Clinic — any institution licensed as a clinic by the Massachusetts Department of Public Health pursuant to M.G.L. c. 111, s. 51 that is not part of a hospital and that possesses its own legal identity, maintains its own patient records, and administers its own budget and personnel. Such institutions include community health centers and mental health centers.

Group Clinic Visit — a session conducted by a physician, physician assistant, nurse practitioner, or registered nurse to introduce preventive medicine approaches to personal health and safety and to present self-help and personal management information concerning family medicine, adult medicine, sex education, and chronic illness.

Health Practitioner — an individual who can diagnose and treat medical problems whether by authority of his or her own license or by the delegated authority of a licensed medical professional.

HIV Pre-Test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, nurse practitioner, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling before HIV testing. Providers will offer information on risk factors and implications of both positive and negative test results, in accordance with established protocols of the Massachusetts Department of Public Health.

HIV Post-Test Counseling Visit — a face-to-face meeting at the CHC between the member and a physician, physician assistant, nurse practitioner, registered nurse, or counselor (working under the supervision of one of the aforementioned) for the purpose of providing counseling after HIV testing. Such counseling will include information about the implications of positive and negative test results, risk-reduction techniques, partner notification, and referral to medical and support services, in accordance with established protocols of the Massachusetts Department of Public Health.

Home Visit — a face-to-face meeting between a member and a physician, physician assistant, nurse practitioner, or registered nurse in the member's residence for examination, diagnosis, or treatment.

Hospital Visit — a face-to-face meeting between a member and a physician, physician assistant, nurse practitioner, or registered nurse when the member has been admitted to a hospital by a physician on the CHC's staff.

Individual Medical Visit — a face-to-face meeting at the CHC between a member and a physician, physician assistant, nurse practitioner, or registered nurse for medical examination, diagnosis, or treatment.

Individual Mental Health Visit — a face-to-face meeting at the CHC between a member and a psychiatrist for mental health examination and diagnosis.

Institutionalized Individual — for purposes of 130 CMR 405.428 through 405.430, an individual who is:

(1) involuntarily confined or detained, under a civil or criminal statute in a correctional or rehabilitative facility, including a psychiatric hospital or other facility for the care and treatment of mental illness; or

(2) confined, under a voluntary commitment, in a psychiatric hospital or other facility for the care and treatment of mental illness.

Mentally Incompetent Individual — for purposes of 130 CMR 405.428 through 405.430, an individual who has been declared mentally incompetent by a federal, state, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes that include the ability to consent to sterilization.

Nursing Facility Visit — a visit by a physician, physician assistant, nurse practitioner, or registered nurse to a member who has been admitted to a nursing facility, extended care facility, or convalescent or rest home.

Primary or Elective Care — medical care required by individuals or families that is appropriate for the maintenance of health and the prevention of illness. This care includes but is not limited to physical examination, diagnosis and management of illness, ongoing health maintenance, accident prevention, and referral when necessary. This care does not require the specialized resources of a hospital emergency department.

Sterilization — any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing. A sterilization is "nontherapeutic" when the individual has chosen sterilization as a permanent method of contraception. A sterilization is "therapeutic" when it occurs as a necessary part of the treatment of an existing illness or injury or is medically indicated and performed in conjunction with surgery upon the genito-urinary tract.

Urgent Care — medical services required promptly to prevent impairment of health due to symptoms that a prudent lay person would believe require medical attention, but are not life-threatening and do not pose a high risk of permanent damage to an individual's health. Urgent care does not include elective or primary care.

405.403: Eligible Members

(A) (1) MassHealth Members. MassHealth covers community health center services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105 specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.

(2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

405.404: Provider Eligibility

Payment for the services described in 130 CMR 405.000 will be made only to providers of community health center services who are participating in MassHealth on the date of service.

(A) In State. To participate in MassHealth, a CHC located in Massachusetts must meet the qualifications for certification or provisional certification in 130 CMR 405.405.

(B) Out of State. To participate in MassHealth, an out-of-state community health center must obtain a MassHealth provider number and meet the following criteria:

(1) if the center is required by its own state's law to be licensed, the center must be licensed by the appropriate state agency under whose jurisdiction it operates;

(2) the center must participate in its state's medical assistance program (or the equivalent); and

(3) the center must have a rate of payment established by the appropriate rate setting regulatory body of its state.

405.405: Certification

(A) Application. An application for certification as a CHC must be made on the form provided by MassHealth and must be submitted to MassHealth's Program Specialist for community health centers. Upon receipt of the completed application, the Program Specialist or his or her designee may arrange a site visit with the applicant to determine compliance with 130 CMR 405.406 through 405.416 inclusive, and if the applicant offers one or more of the services described in 130 CMR 405.431 through 405.471, compliance with the applicable portions of those sections. Based on the information revealed by the application and the site visit, MassHealth will determine whether the applicant is certifiable, provisionally certifiable, or not certifiable. The Program Specialist will promptly notify the applicant of the determination in writing. If the applicant is not certifiable, the notice will contain a statement of the reasons for that determination.

(B) Certification. A determination of certifiability indicates that the applicant has been found by MassHealth to be in compliance with 130 CMR 405.406 through 405.416 inclusive and, to the extent applicable, with 130 CMR 405.431 through 405.471. Upon such determination of certifiability, the CHC may enter into a provider agreement with MassHealth in accordance with MassHealth regulations in 130 CMR 450.000.

(C) Provisional Certification. Provisional certification means that MassHealth has determined the applicant to be in compliance with the sections referred to in 130 CMR 405.405(B) above except for one or more of the following: 130 CMR 405.408(F) (Nutrition Services), 130 CMR 405.408(C) (Obstetrics/Gynecology), 130 CMR 405.414 (Translation Services), or 130 CMR 405.415 (Emergency Backup Services). If an applicant has been provisionally certified, the letter of notification will specify the certification requirements with which the applicant has failed to comply and the schedule for achieving compliance. When requirements for full certification have been met, MassHealth will certify the CHC. Upon notice of provisional certification, the CHC may enter into a provider agreement with MassHealth in accordance with MassHealth regulations in 130 CMR 450.000, on the condition that such provider agreement, by its own terms, will expire upon the date fixed in the letter of notification for full compliance.

(D) Review of Certification.

(1) MassHealth's Program Specialist for community health centers has the right to review a certified or provisionally certified provider's continued compliance with the conditions for certification referred to in 130 CMR 405.405(A), (B), and (C) upon reasonable notice and at any reasonable time during the hours of operation of the provider. The Program Specialist has the right to revoke the certification or provisional certification of a provider, subject to any applicable provisions of MassHealth regulations in 130 CMR 450.000, if such review reveals that the provider has failed or ceased to meet such conditions.

(2) Any changes in the manager or professional services director or in the scope of services provided by a CHC must be reported in writing to MassHealth's Program Specialist for community health centers. Any additions to the scope of services must be approved in writing by the Program Specialist before they are reimbursable by MassHealth. Deletions of services may result in review of the CHC by MassHealth to determine whether the CHC still meets the requirements for certification set forth in 130 CMR 405.405.

405.406: Administrative Requirements

A CHC must meet the administrative requirements specified in 130 CMR 405.406 to receive certification as outlined in 130 CMR 405.405.

(A) Licensing. The CHC must be licensed as a clinic by the Massachusetts Department of Public Health. For the purposes of 130 CMR 405.000, the term "licensee" means the entity named in the license issued by the Department of Public Health.

(B) Nonprofit Status. The CHC must be a nonprofit organization.

(C) Staffing.

(1) The CHC must employ an on-site manager who is qualified by education, training, or experience to serve as the administrator of the CHC. The manager is responsible to the licensee for both the management and administration of CHC services, for carrying out policies established or approved by the licensee, and for ensuring that the CHC complies with 130 CMR 405.000.

(2) The CHC must employ a professional services director who is a health practitioner qualified by education, training, or experience to direct and evaluate the provision of health services in the CHC. The professional services director must supervise the staff members providing health services and must ensure that treatment and care are both adequate and appropriate to the needs of members and are in compliance with 130 CMR 405.000. The professional services director must be either on site or on call at all times that the CHC is in operation.

(3) The same individual may serve as both the manager and the professional services director, if this individual meets the requirements in 130 CMR 405.406(C)(1) and (2).

(D) Minimum Hours. The CHC must be open for the delivery of medical services to the public on a regular schedule for a minimum of 20 hours per week. The schedule must be arranged to afford maximum access to members, such as by regularly scheduled evening or weekend clinic hours.

(E) Governing Board. The CHC must have a governing or advisory board that includes at least one person who regularly uses the services of the CHC. This person may not be employed by the CHC or the licensee while a member of the board. Matters subject to review by the board must include, but are not necessarily limited to, scope of services, budget, personnel policies, and program evaluation.

(F) Member Grievances. The CHC must have established written procedures for accepting, processing, and responding to member grievances.

405.407: Physician Time Required on Site

Except as specified in 130 CMR 405.407(A) and (B), a CHC must have at least one licensed physician on site during its hours of operation to treat medical problems outside the expertise of other health practitioners on the CHC's staff. This physician may leave the CHC for limited periods to visit CHC patients in their homes, in hospitals, or in nursing facilities; but he or she must be on call to the CHC during such periods.

(A) CHCs that are located in isolated rural areas where no licensed physician is available on a regular basis within a 20-mile radius and that have a licensed physician on call during all hours of operation may apply to the Division's Program Specialist for community health centers for a waiver of this requirement.

(B) CHCs that employ family practitioners on site may substitute family practitioners for other specialists who are unavailable due to the center's geographic isolation, but whose specialized services must be provided on site. These specialties include pediatrics, obstetrics/gynecology, and internal medicine.

405.408: Medical Services Required on Site

A CHC must provide on site the medical services specified in 130 CMR 405.408. It is not necessary that all of these services be available during all hours of the CHC's operation, but all must be available to members on a regularly scheduled basis with sufficient frequency to ensure access to care and continuity of care. If the CHC does not serve patients of a particular age group, upon the prior written approval of the Division, the CHC will not be required to provide pediatric or obstetrical/gynecological services or both (see 130 CMR 405.408(A) and (C)).

(A) Pediatric Services. A CHC must provide pediatric services.

(B) Internal Medicine. A CHC must provide internal medicine services.

(C) Obstetrics/Gynecology. A CHC must provide obstetrical and gynecological services. When a family practitioner is employed in place of a specialist in obstetrics/gynecology, the family practitioner must have admitting privileges to a hospital for delivery and obstetrical and gynecological backup.

(D) Health Education. A CHC must provide health education designed to prepare members for their participation in and reaction to specific medical procedures, and to instruct members in self-management of medical problems and in disease prevention. Health education may be provided by any health practitioner or by any other individual approved by the professional services director as possessing the qualifications and training necessary to provide health education to members.

(E) Medical Social Services. A CHC must provide medical social services designed to assist members in their adjustment to and management of social problems resulting from medical treatment, specific disease episodes, or chronic illness. Medical social services must be provided by a clinical social worker who is licensed by the Massachusetts Board of Registration. This individual must be on site sufficient hours and with sufficient frequency to provide medical social services to members.

(F) Nutrition Services. A CHC must provide counseling in the purchase, preparation, and consumption of proper nutrients to members who have been determined to require such counseling because of their health problems or because they have a high potential for developing health problems that might be avoided or made less severe through proper nutrition. Each CHC must employ either a nutrition professional with a bachelor's or master's degree in public health nutrition, community nutrition, or human nutrition; or a dietitian who is currently registered by the American Dietetic Association. This individual is responsible for planning, directing, and evaluating the nutrition services provided at the CHC; for educating the CHC's staff about nutrition; for supervising any nutrition aides; for consulting with practitioners and other staff members of the CHC; and for counseling members referred for nutrition information. The nutrition professional or registered dietitian must be on site at least one day per calendar month.

405.409: Medical Services Required on Site or by Referral

All of the services listed in 130 CMR 405.409 must be provided on site or, alternatively, through a referral network. With the exception of audiology, electrocardiogram, laboratory, and radiology services, the CHC must notify the Division, in writing, of each service listed below that the CHC will provide on site. All services provided on site must be furnished and payment claimed in compliance with the applicable MassHealth regulations for each service, including applicable fee schedules. All services provided by referral must be based on written agreements between the CHC and each referral provider to ensure continuity of care, exchange of relevant health information such as test results and records, and avoidance of service duplication. Each referral provider must be a participating provider in MassHealth. All referrals must include follow-up to ensure that the referral process is successfully completed. Services that must be provided on site or through the referral network are the following:

(A) audiology services;

(B) Chapter 766 core evaluations;

(C) dental services;

(D) electrocardiogram (EKG) services;

(E) home health services;

(F) laboratory services;

(G) medical specialty services such as, but not limited to, cardiology and neurology;

(H) mental health center services, including psychological testing;

(I) occupational therapy services;

(J) pharmacy services;

(K) physical therapy services;

(L) podiatry services;

(M) radiology services;

(N) speech/language therapy services; and

(O) vision care services.

405.410: Subcontracting for Dental Services

(A) In addition to the circumstances described in 130 CMR 405.409, dental services may be provided through subcontracts with dental practitioners not participating in MassHealth. All subcontracts between the CHC and a dental practitioner must be in writing, ensure continuity of care, and be consistent with all applicable provisions of 130 CMR 405.000. The CHC must submit a copy of any such subcontract to the Division.

(B) The CHC is legally responsible to the Division for the performance of any subcontractor. The CHC must ensure that every subcontractor is licensed by the Massachusetts Board of Registration in Dentistry, and that services are furnished in accordance with the Division's dental regulations at 130 CMR 420.000 and all other applicable MassHealth requirements, including, but not limited to, those set forth in 130 CMR 450.000. The CHC must submit claims for payment for dental services provided hereunder in accordance with the Division's dental regulations at 130 CMR 420.000, including applicable fee schedules.

405.411: Continuity of Care

A CHC must maintain continuity of care in providing health services to members. Continuity of care ensures that a member will always be seen by a health practitioner knowledgeable about the member's case. Mere access to medical records by all practitioners who deliver services to a member will not suffice as a means of complying with 130 CMR 405.411.

405.412: Recordkeeping Requirements

(A) A CHC must comply with the Division's recordkeeping regulation contained in 130 CMR 450.000. In addition, each member's medical record must include the reason for each visit and the data upon which the diagnostic impression or statement of the member's problem is based, and must be sufficient to justify any further diagnostic procedures, treatments, and recommendations for return visits or referrals. Specifically, a medical record must include, but not be limited to:

(1) the date of each service;
(2) the member's name and date of birth;
(3) the signature and title of the person performing the services;
(4) the member's medical history;
(5) the diagnosis or chief complaint;
(6) clear indication of all findings, whether positive or negative, on examination;
(7) any medications administered or prescribed, including strength, dosage, and regimen;
(8) a description of any treatment given;
(9) recommendations for additional treatments or consultations, when applicable;
(10) any medical goods or supplies dispensed or prescribed;
(11) any tests administered and their results;
(12) a notation of hospitalization ordered by a CHC practitioner and discharge summaries from such hospitalization; and
(13) notations of all referrals and results of referrals, including the referral provider's diagnoses, treatment plans, test results, and medical outcomes.

(B) Basic data collected during previous visits (for example, identifying data, chief complaint, and history) need not be repeated in the member's medical record for subsequent visits. However, data that fully document the nature, extent, quality, and necessity of care furnished to a member must be included for each service for which payment is claimed, along with any data that update the member's medical course. It is not necessary to include a full medical history in the medical record for any member who is seen by the CHC on a one-time emergency basis.

(C) For hospital visit services, there must be an entry in the hospital medical record corresponding to and substantiating each hospital visit for which payment is claimed. An inpatient medical record documents services provided to members and billed to the Division if it conforms to and satisfies the medical records requirements set forth in the current Rules and Regulations for Hospitals in Massachusetts issued by the Massachusetts Department of Public Health. The CHC claiming payment for a hospital inpatient visit is responsible for the adequacy of the medical record documenting such visit. The physician must sign the entry in the hospital medical record that documents the findings of the comprehensive history and physical examination.

(D) Additional medical records requirements for other services can be found in the applicable sections of the Division's regulations.

405.413: Coordination of Services

A CHC that provides any of the services listed in 130 CMR 405.409 or 405.471 must coordinate these services with all other services at the CHC. Such coordination includes at a minimum:

(A) one central medical record for each member in which all health care services are recorded;

(B) medical accountability to the CHC's professional services director;

(C) administrative accountability to the CHC's manager;

(D) participation in the CHC's quality assessment program (if the special group of services has its own plan for quality assessment, this plan must be approved by the professional services director who must also receive progress reports);

(E) regular participation in the CHC's staff meetings and other appropriate activities by those professionals responsible for directing special services; and

(F) familiarization with the CHC's policies, procedures, staff, and scope of services by all personnel employed through special programs.

405.414: Translation Services

A CHC must employ at least one practitioner or translator conversant in the primary language of each substantial population (10 percent or more of the total member population) of non-English-speaking members that regularly uses the CHC.

405.415: Emergency Backup Services

(A) A CHC must provide either:
(1) 24-hour-a-day on-site medical or emergency services or both; or
(2) an after-hours telephone service, and have a written agreement with a provider of 24-hour-a-day medical or emergency service or both.

(B) A tape-recorded telephone message instructing members to call an emergency backup provider or a hospital emergency room does not suffice as compliance with the requirement of 130 CMR 405.415(A).

405.416: Quality Assessment Program

(A) A CHC must have in effect a program for internal quality assessment that is based on written policies, standards, and procedures, and that includes the following:

(1) a review of the CHC's performance including, but not limited to, adequacy of recordkeeping, referral procedures and follow-up, medication review, quality of patient care, and identification of deficient areas of performance;

(2) recommendations for correcting any deficiencies identified in the review; and

(3) a review of any such corrective action.

(B) These reviews must be conducted at least twice a year by a committee composed of the professional services director, representatives of each professional discipline on the CHC's staff, consumers, and, if possible, health professionals not employed at the CHC. Activities of the committee must be documented in minutes or a report and made available to the Division upon request.

405.417: Maximum Allowable Fees

The Massachusetts Division of Health Care Finance and Policy determines the maximum allowable fees for CHC services. Payment is always subject to the conditions, exclusions, and limitations set forth in 130 CMR 405.000. The maximum allowable fees for CHC services are the lowest of the following:

(A) the CHC's usual and customary fee;

(B) the CHC's actual charge submitted; or

(C) the maximum allowable fee listed in the applicable Division of Health Care Finance and Policy fee schedule.

405.418: Nonreimbursable Services

(A) The Division will not pay a CHC for performing, administering, or dispensing experimental, unproven, or otherwise medically unnecessary procedures or treatments, specifically including, but not limited to, sex-reassignment surgery, thyroid cartilage reduction and any other related surgeries and treatments including pre- and post-sex-reassignment surgery hormone therapy. Notwithstanding the preceding sentence, the Division will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993.

(B) The Division will not pay a CHC for the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

(130 CMR 405.419 and 405.420 Reserved)

405.421: Visits: Service Limitations

The following restrictions and limitations apply to visits as defined in 130 CMR 405.402.

(A) Individual Medical Visit. An individual medical visit may not be used for mental health services or for HIV pre- or post-test counseling visits.

(B) Individual Mental Health Visit. An individual mental health visit conducted by a person other than a psychiatrist (for example, a psychologist, nurse, physician assistant, social worker, or counselor) is not reimbursable. An individual mental health visit must be for the sole purpose of examination and diagnosis, and must not include mental health treatment.

(C) Group Clinic Visit. All instructional group sessions for members must be carried out by a physician, nurse practitioner, registered nurse, or physician assistant. A group visit conducted by other kinds of professionals (for example, social workers, counselors, or nutritionists) is not reimbursable as a group clinic visit.

(D) HIV Pre- and Post-Test Counseling Visits. The CHC may be reimbursed for a maximum of two HIV pre-test counseling and two HIV post-test counseling visits per member per test. A maximum of four pre-test counseling visits and four post-test counseling visits per calendar year per member are reimbursable.

(E) Home Visit. A home visit must be used to deliver episodic care in the member's home when a health practitioner has determined that it is not advisable for the member to visit the CHC. The medical record must document the reasons for a home visit. A house-bound member with chronic medical and nursing care needs must be referred to a Medicare-certified home health agency.

(F) Treatments or Procedures. The CHC may bill for a visit, a treatment, or a procedure, but may not bill for more than one of these services provided to the same member on the same date when the services are performed in the same location. Examples of treatments or procedures are a vasectomy or an amniocentesis.

(G) Urgent Care. The Division will pay an enhanced fee for urgent care when such care is provided at the CHC Monday through Friday from 5:00 P.M. to 6:59 A.M., and from Saturday at 7:00 A.M. through Monday at 6:59 A.M.

405.422: Obstetric Services: Introduction

(A) The Division offers two methods of reimbursement for obstetric services: the fee-for-service method and the global fee method. Fee for service requires submission of claims for services as they are performed and is always available for reimbursable obstetric services. The global fee method is available only when the conditions in 130 CMR 405.423 are met. Global fee offers two options: the standard global fee and the enhanced global fee. (See 130 CMR 405.424 and 405.425.)

(B) The Division will pay for a delivery performed in a hospital by a physician or, in the case of a pelvic delivery, by a nurse midwife who meets the requirements in 130 CMR 405.427 when the physician or nurse midwife is a contractor or employee of the CHC. Such a delivery is reimbursable provided that such a contractor or employee is not receiving a salary from a hospital or other institution to perform the same service. For each such delivery, the CHC may claim payment for the services of only one practitioner (that is, a CHC may not submit two claims for one delivery—one for a physician and one for a nurse midwife).

405.423: Obstetric Services: Global Fee Method of Reimbursement

(A) Definition of Global Fee. The global fee is a single inclusive fee for all prenatal visits, the delivery, and one postpartum visit. The two global fee options (standard global fee and enhanced global fee) are available only when the conditions in 130 CMR 405.423 are met. The two options are fully defined in 130 CMR 405.424 and 405.425.

(B) Conditions for Global Fee.

(1) Only the CHC may claim payment of the global fee. To qualify to receive a global fee payment, the CHC must coordinate a minimum of six prenatal visits, the delivery, and postpartum care, provided by a physician, a nurse, a nurse practitioner, a nurse midwife, or a physician assistant who is qualified to perform such services and is a contractor or employee of the CHC. Such an employee or contractor must not be receiving a salary from a hospital or institution to perform the same service. For example, if a staff physician from a hospital performs a delivery while on hospital salary for that service, the CHC must not bill for the global fee for that delivery, but may bill fee for service for the medical visits. However, those visits are not reimbursable if provided by someone receiving a hospital or institutional salary to perform the same service.

(2) All the components of a global fee must be provided at a level of quality consistent with the standards of practice of the American College of Obstetrics and Gynecology.

(C) Multiple Providers. When more than one provider is involved in prenatal, delivery, and postpartum services for the same member, the following conditions apply.

(1) The global fee may be claimed only by the CHC and only if the required services (minimum of six prenatal visits, the delivery, and postpartum care) are provided directly by a physician, a nurse, a nurse practitioner, a nurse midwife, or a physician assistant who is qualified to perform such services and is a contractor or employee of the CHC.

(2) If the CHC bills for the global fee, any provider who is not a contractor or employee of the CHC, but who performed prenatal visits or postpartum visits for the member may claim payment for such services only on a fee-for-service basis. If the CHC bills for the global fee, no other provider may claim payment for the delivery.

(3) If the CHC bills on a fee-for-service basis, any other provider may claim payment on a fee-for-service basis for prenatal, delivery, and postpartum services provided to the same member.

(D) Recordkeeping for Global Fee. The CHC is responsible for documenting, in accordance with 130 CMR 405.412, all the service components of a standard or enhanced global fee; this includes services performed by contractors and employees of the CHC. A member's risk assessment and all her medical visits must be recorded in a way that allows for easy review of her obstetrical history. Hospital and ambulatory services must be clearly documented in each global fee member's record.

405.424: Obstetric Services: Standard Global Fee

The standard global fee is an all-inclusive fee for all prenatal visits, the delivery, and one postpartum visit. The CHC must perform or coordinate a minimum of six prenatal visits, the delivery, and postpartum care to claim the standard global fee; for a CHC, the global fee includes payment for the delivery (Caesarean or pelvic), all prenatal visits, and one postpartum visit.

405.425: Obstetric Services: Enhanced Global Fee

The enhanced global fee includes all the components of the standard global fee (a minimum of six prenatal visits, the delivery, and postpartum care), and requires three additional categories of service as a condition for payment. These three categories are coordinated medical management, health-care counseling, and obstetrical-risk assessment and monitoring. The CHC must develop a plan of care, documented in the member's medical record, for each enhanced global delivery member; the plan of care must include services in each category that are relevant to the member's condition.

(A) Coordinated Medical Management. The CHC must provide referral to and coordination of the medical and support services necessary for a healthy pregnancy and delivery. This includes the following:

(1) tracking and follow-up of the patient's activity to ensure completion of the patient care plan, with the appropriate number of visits;
(2) coordination of medical management with necessary referral to other medical specialties and dental services; and
(3) referral to WIC (the Special Supplemental Food Program for Women, Infants, and Children), counseling, and social work as needed.

(B) Health-Care Counseling. In conjunction with providing prenatal care, the CHC must provide health-care counseling to the woman over the course of the pregnancy. Topics covered must include, but are not limited to, the following:

(1) EPSDT screening for teenage pregnant women;
(2) smoking and substance abuse;
(3) hygiene and nutrition during pregnancy;
(4) care of breasts and plans for infant feeding;
(5) obstetrical anesthesia and analgesia;
(6) the physiology of labor and the delivery process, including detection of signs of early labor;
(7) plans for transportation to the hospital;
(8) plans for assistance in the home during the postpartum period;

(9) plans for pediatric care for the infant; and
(10) family planning.

(C) Obstetrical-Risk Assessment and Monitoring. The CHC must manage the member's obstetrical-risk assessment and monitoring. Medical management requires monitoring the woman's care and coordinating diagnostic evaluations and services as appropriate. The professional and technical components of these services will be reimbursed separately and should be billed for on a fee-for-service basis. Such services may include, but are not limited to, the following:
(1) counseling specific to high-risk patients (for example, antepartum genetic counseling);
(2) evaluation and testing (for example, amniocentesis); and
(3) specialized care (for example, treatment of premature labor).

405.426: Obstetric Services: Fee-for-Service Method of Reimbursement

The fee-for-service method of reimbursement is always available to a provider for obstetric services reimbursable under MassHealth. If the global fee requirements in 130 CMR 405.423 are not met, the provider or providers may claim payment from the Division only on a fee-for-service basis, as specified below.

(A) If the pregnancy is terminated by an event other than a delivery, each provider involved in performing obstetric services for the member may claim payment only on a fee-for-service basis.

(B) When additional services (for example, ultrasound or special tests) are performed, the provider may claim payment for these only on a fee-for-service basis.

405.427: Nurse-Midwife Services

(A) Reimbursable Services. The CHC may bill for services provided by a nurse midwife that relate to pregnancy, labor, birth, and the immediate postpartum period when the nurse midwife is a contractor or employee of the CHC. The following conditions also apply.
(1) The services must be limited to the scope of practice authorized by state law or regulation.
(2) The nurse midwife must meet the educational and certification requirements mandated by state law or regulation.
(3) The nurse midwife must enter into a formal collaborative arrangement with a physician or group of physicians as required by state law or regulation.
(4) The immediate postpartum period during which nurse-midwife services may be provided is defined as a period of time not to exceed six weeks after the date of delivery.
(5) Deliveries by a nurse midwife must occur in facilities licensed by the Department of Public Health for the operation of maternity and newborn services.

(B) Nonreimbursable Services.

(1) Childbirth education classes are not reimbursable.

(2) Prenatal or postpartum care provided by a nurse midwife in the member's home is not reimbursable.

(C) Educational and Certification Requirements. A nurse midwife on the staff of a CHC must have successfully completed a formal educational program for nurse midwives as required by the Massachusetts Board of Registration in Nursing.

(1) A nurse midwife who has completed such educational requirements may provide services to members prior to the first certification examination for which the nurse midwife is eligible.

(2) If the scheduled examination is missed, the nurse midwife must immediately cease providing services to members.

(3) Upon receiving notice of failure to pass the examination, the nurse midwife must immediately cease providing services to members.

(4) After passing the examination, the nurse midwife must be certified to practice by the Board of Registration in Nursing.

(5) When such certification expires or is suspended, the nurse midwife must immediately cease providing services to members.

405.428: Sterilization Services: Introduction

(A) Reimbursable Services. The Division will pay for a sterilization service provided to an eligible member only if all of the following conditions are met.

(1) The member has voluntarily given informed consent for the sterilization procedure in the manner and at the time described in 130 CMR 405.429, and such consent is documented in the manner and form described in 130 CMR 405.430.

(2) The member is at least 18 years old at the time consent is obtained.

(3) The member is not a mentally incompetent or institutionalized individual.

(B) Assurance of Member Rights. No provider may use any form of coercion in the provision of sterilization services. No provider, or agent or employee of a provider, may mislead any member into believing that a decision to have or not to have a sterilization will adversely affect the member's entitlement to benefits or services for which the member would otherwise be eligible.

(C) Retroactive Eligibility. The Division will not pay for a sterilization performed during the period of a member's retroactive eligibility unless all conditions for payment listed in 130 CMR 405.428(A) are met.

(D) Location in Which Sterilizations May Be Performed.

(1) Male sterilization must be performed by a licensed physician at the CHC.

(2) Female sterilization must be performed by a licensed physician in an inpatient hospital.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 405.000)	PAGE 4-17
COMMUNITY HEALTH CENTER MANUAL	TRANSMITTAL LETTER CHC-57	DATE 01/01/98

405.429: Sterilization Services: Informed Consent

A member's consent for sterilization will be considered informed and voluntary only if such consent is obtained in accordance with the requirements specified in 130 CMR 405.429(A) and (B).

(A) Informed Consent Requirements.

(1) The person who obtains consent (a physician, nurse, or counselor, for example) must orally provide all of the following information and advice to the member requesting sterilization:

(a) advice that the member is free to withhold or withdraw consent for the sterilization procedure at any time prior to that procedure without affecting the right to future care or treatment and without loss of any federal- or state-funded program benefits to which the member might be entitled;

(b) a description of available alternative methods of family planning and birth control;

(c) advice that the sterilization procedure is considered irreversible;

(d) a thorough explanation of the specific sterilization procedure to be performed;

(e) a full description of the benefits or advantages that may be expected as a result of the sterilization; and

(f) advice that the sterilization will not be performed for at least 30 days from the date consent is given.

(2) The person who obtains consent must also:

(a) offer to answer any questions the member may have concerning the sterilization procedure;

(b) give the member a copy of the consent form;

(c) make suitable arrangements to ensure that the information and advice required by 130 CMR 405.429(A)(1) are effectively communicated to any member who is blind, deaf, or otherwise handicapped;

(d) provide an interpreter if the member does not understand the language used on the consent form or the language used by the person obtaining consent; and

(e) allow the member to have a witness of the member's choice present when consent is obtained.

(B) When Informed Consent Must Be Obtained.

(1) A member's consent for sterilization will be considered informed and voluntary only if such consent is obtained at least 30 days, but not more than 180 days, before the date of the sterilization procedure.

(2) A member's consent for sterilization will not be considered informed or voluntary if such consent is obtained or given while the member requesting sterilization is under the influence of alcohol or other substances that affect the individual's state of awareness.

(3) Shortly before the performance of the sterilization procedure, the physician performing the procedure must orally inform the member of all the information and advice specified in 130 CMR 405.429(A)(1).

405.430: Sterilization Services: Consent Form Requirements

Informed consent for sterilization must be documented by the completion of the Division's Consent for Sterilization form in accordance with the following requirements. (Instructions for obtaining the Consent for Sterilization forms are located in Subchapter 5 of the *Community Health Center Manual*.)

(A) Required Consent Form.
(1) One of the following Consent for Sterilization forms must be used:
(a) CS-18 for members aged 18 through 20; or
(b) CS-21 for members aged 21 and older.
(2) Under no circumstances will the Division accept any other consent for sterilization form.

(B) Required Signatures. The member, the interpreter (if one was required), and the person who obtained the consent for sterilization must all sign and date the Consent for Sterilization for (CS-18 or CS-21) at the time of consent. After performing the sterilization procedure, the physician must sign and date the form.

(C) Required Submission and Distribution of the Consent Form. Providers must complete and distribute the Consent for Sterilization form (CS-18 or CS-21) as follows:
(1) the original to the member at the time of consent;
(2) a copy in the member's permanent record at the site where the sterilization is performed; and
(3) a copy of the completed Consent for Sterilization form (CS-18 or CS-21) attached to each claim made to the Division for sterilization services.

405.431: Laboratory Services: Introduction

In order for a CHC to be paid for any laboratory service, a written request for that service from an authorized prescriber must be present in the member's medical record.

405.432: Laboratory Services: Eligibility to Provide Services

A CHC may claim payment for the laboratory tests listed in Subchapter 6 of the *Community Health Center Manual* only when all of the following conditions are met.

(A) The laboratory tests are performed in the CHC.

(B) The tests are performed on properly and regularly calibrated equipment, and daily controls are carried out.

(C) The laboratory participates in an external proficiency-testing program for any tests it is performing. It must be demonstrated that the CHC's laboratory performance is satisfactory according to any of the following proficiency-testing programs:

(1) the American Association of Bioanalysts Program;
(2) the State Laboratory Improvement Program; and
(3) the College of American Pathologists Program.

Other proficiency-testing programs may be acceptable, but only upon the express written approval of the Division's Program Specialist for laboratory services.

405.433: Laboratory Services: Service Limitations

(A) The Division will not pay a CHC for the following services: routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue); laboratory tests associated with male or female infertility; or such calculations as red cell indices, A/G ratio, creatinine clearance, and those ratios calculated as part of a profile. The Division will not pay a CHC for a laboratory service when the CHC bills separately for the professional component of that service.

(B) The Division will pay a CHC for the professional component of an anatomical service separately, as provided in Subchapter 6 of the *Community Health Center Manual* (for example, bone marrow analysis, analysis of surgical specimen).

(C) A profile or panel test is defined as any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics.

(1) The group of tests is designated as a profile or panel by the CHC performing the tests.
(2) The group of tests is performed by the CHC at a usual and customary fee that is lower than the sum of that CHC's usual and customary fees for the individual tests in that group.

In no event may a CHC bill or be paid separately for each of the tests included in a profile test when a profile test has either been performed by that CHC or requested by an authorized person.

(D) Some services listed in Subchapter 6 of the *Community Health Center Manual* are designated "I.C.," an abbreviation for individual consideration. This means that a specific fee could not be established. The payment for an I.C. service will be determined by the Division based on the designation of the test as entered on the claim form.

(E) A CHC may not bill for a visit when a member is being seen for laboratory services only.

Commonwealth of Massachusetts Division of Medical Assistance Provider Manual Series COMMUNITY HEALTH CENTER MANUAL	SUBCHAPTER NUMBER AND TITLE 4 PROGRAM REGULATIONS (130 CMR 405.000)	PAGE 4-20
	TRANSMITTAL LETTER CHC-57	DATE 01/01/98

405.434: Laboratory Services: Services Performed by Outside Laboratories

(A) Except for the circumstance described in 130 CMR 405.434(C), a CHC may not bill the Division for laboratory services provided outside the CHC. In this case, the testing laboratory should bill the Division directly for those services.

(B) When sending a specimen to an outside laboratory, the CHC must include the member's MassHealth identification number and the CHC's MassHealth provider number.

(C) A CHC may bill the Division for laboratory services provided on a fee-for-service basis by the state laboratory of the Massachusetts Department of Public Health.

(130 CMR 405.435 through 405.440 Reserved)

405.441: Radiology Services: Introduction

The Division will pay for the radiology services in Subchapter 6 of the *Community Health Center Manual* only when the services are provided at the written request of a licensed physician or dentist. All radiology equipment used in providing these services must be inspected and approved by the Massachusetts Department of Public Health.

405.442: Radiology Services: Service Limitations

(A) Definitions.

Global Fee – the rate of payment for the two components of a radiology service: the professional component and the technical component.

Professional Component – the component of a radiology service for interpreting a diagnostic test or image.

Technical Component – the component of a radiology service for the cost of rent, equipment, utilities, supplies, administrative and technical salaries and benefits, and other overhead expenses.

(B) Payment of the Global Fee. The Division will pay a CHC the global fee for performing a radiology service at the CHC when one of the following conditions is met.

(1) The CHC owns or leases the equipment for providing the technical component of the service, employs a technician to provide the technical component of the service, and employs a board-certified or board-eligible radiologist to provide the professional component of the service.

(2) The CHC employs a board-certified or board-eligible radiologist to provide the professional component of the service and the CHC subcontracts with a licensed Medicare-certified entity to provide the technical component of the service.

(3) The CHC subcontracts with a licensed Medicare-certified entity to provide the professional and technical component of the service.

(C) Subcontracting for Radiology Services.

(1) All subcontracts between the CHC and the licensed Medicare-certified entity must be in writing, ensure continuity of care, and be consistent with all applicable provisions of these regulations.

(2) The CHC is legally responsible to the Division for the performance of any subcontractor. The CHC must ensure that every subcontractor is licensed and Medicare-certified, and that services are furnished in accordance with the Division's regulations, including, but not limited to, those set forth in 130 CMR 450.000. The CHC must submit claims for payment for radiology services provided hereunder in accordance with the Division's regulations and applicable fee schedules.

(D) Radiology Recordkeeping (Medical Records) Requirements. In addition to complying with the general recordkeeping requirements (see 130 CMR 405.412), the CHC must keep records of radiology services performed. All X rays must be labeled with the following:

(1) the member's name;
(2) the date of the examination;
(3) the nature of the examination; and
(4) left and right designations and patient position, if not standard.

405.443: Radiology Services: Payment Limitations

(A) The maximum allowable fees include payment for both the technical and professional components of the radiology service. A CHC must not bill for either the professional or technical component separately.

(B) Radiology services that are not listed in Subchapter 6 of the *Community Health Center Manual* are not reimbursable when furnished in a CHC. The CHC should refer a member to a hospital for such services.

(C) Some services listed in Subchapter 6 of the *Community Health Center Manual* are designated "S.P.," an abbreviation for separate procedure. Radiology services that are performed at separate sittings on the same or different days are considered separate procedures. The CHC must not bill separately for a service listed as an S.P. service when this service is furnished as a portion of another radiology service at the same sitting.

(D) A CHC must not bill for a visit when a member is being seen for a radiology service only.

(130 CMR 405.444 through 405.450 Reserved)

405.451: Electrocardiogram (EKG) Services: Introduction

The MassHealth agency will pay for an electrocardiogram (EKG) service only when the service is provided at the written request of a CHC staff physician who will interpret or review the interpretation of the EKG. Documentation of the physician's request must be kept in the member's medical record.

405.452: Electrocardiogram (EKG) Services: Eligibility to Provide Services

A CHC may claim payment for electrocardiogram (EKG) services only when both of the following conditions are met.

(A) The CHC owns or rents its own EKG equipment.

(B) The EKG is taken at the CHC or at the member's home.

405.453: Electrocardiogram (EKG) Services: Payment Limitations

(A) The maximum allowable fees include payment for both the technical and professional components of the service. The test must be performed at the CHC and interpreted by a physician employed by the CHC.

(B) A CHC must not bill for a visit when a member is being seen for an EKG only.

(130 CMR 405.454 through 405.460 Reserved)

405.461: Audiology Services: Introduction

In order for a CHC to be paid for an audiology service other than a hearing test performed as part of an EPSDT services assessment (see 130 CMR 450.140 through 450.149), a written request must be made by a physician, nurse practitioner, or physician assistant who has found some indication of a hearing problem. Documentation of the request and of the hearing problem must be kept in the member's medical record.

405.462: Audiology Services: Eligibility to Provide Services

(A) A CHC may claim payment for a basic pure-tone (air and bone) evaluation by audiometer furnished to a member only when the following conditions are met.

(1) The CHC possesses on its premises a pure-tone audiometer, which must be calibrated at least once every six months. Records of calibrations must be kept and made available to the MassHealth agency upon request. The machine must be placed and testing conducted in a quiet room.

(2) The person conducting hearing evaluations is trained to perform hearing tests with an audiometer.

(3) The quality of the tester's work is assessed at least twice a year by an audiologist licensed or certified in accordance with 130 CMR 426.404. The audiologist may be a consultant to the CHC.

(B) A CHC may claim payment for conducting acoustic impedance testing only when the following conditions are met.

(1) The test is conducted by an ASLHA-certified audiologist on the premises of the CHC.

(2) The test is conducted by means of a functioning impedance bridge that is placed in a quiet room.

(C) If a problem or abnormality is detected or believed to be present after completion of either the basic pure-tone evaluation or the acoustic impedance test or both, the member must be referred to an otologist or an otolaryngologist for a more complete audiological evaluation and treatment as necessary.

405.463: Audiology Services: Payment Limitations

(A) Audiology services that are not listed in Subchapter 6 of the *Community Health Center Manual* are not reimbursable when furnished in a CHC.

(B) A CHC must not bill for a visit when a member is seen for audiology services only.

(130 CMR 405.464 and 405.465 Reserved)

405.466: Pharmacy Services: Participation in the 340B Drug-Pricing Program for Outpatient CHC Pharmacies

(A) Notification of Participation. A CHC that is a 340B-covered entity may provide drugs to MassHealth members through the 340B drug-pricing program provided that it notifies MassHealth by submitting to MassHealth a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and, if applicable, a copy of the OPA form used to certify the contracted pharmacy services. The CHC may provide and bill for 340B drugs to MassHealth members, provided directly or through a subcontract, after MassHealth confirms, in writing, its receipt of the CHC's notification and copy of its OPA registration form, in accordance with 130 CMR 405.466(A).

(B) Subcontracting for 340B Outpatient CHC Pharmacy Services.

(1) A CHC that is a 340B-covered entity may contract with a MassHealth pharmacy provider to dispense 340B drugs for the 340B-covered entity's MassHealth patients. All such subcontracts between the 340B-covered entity and a pharmacy provider must be in writing, ensure continuity of care, specify that the CHC pays the pharmacy, specify that such payment constitutes payment in full for 340B drugs provided to MassHealth members, be consistent with all applicable provisions of 130 CMR 406.000, and are subject to MassHealth approval. The 340B-covered entity must comply with the requirements of 130 CMR 405.466(A) by submitting to MassHealth a copy of the form used to register with the Health Resources and Services Administration, Office of Pharmacy Affairs (OPA), as a 340B-covered entity and a copy of the OPA form used to certify the contracted pharmacy services for the 340B drug-pricing program.

(2) The CHC is legally responsible to MassHealth for the performance of any subcontractor. The CHC must ensure that every pharmacy subcontractor is licensed by the Massachusetts Board of Registration in Pharmacy, is a MassHealth pharmacy provider, and that services are furnished in accordance with MassHealth pharmacy regulations at 130 CMR 406.000 and all other applicable MassHealth requirements, including but not limited to, those set forth in 130 CMR 450.000.

(C) Termination or Changes in 340B Drug-Pricing Program Participation. A CHC must provide MassHealth 30 days' advance written notice of its intent to discontinue, or change in any way material to MassHealth, the manner in which it provides 340B outpatient drugs for its MassHealth patients.

(D) Payment for 340B Outpatient CHC Pharmacy Services. MassHealth pays the 340B-covered entity for outpatient CHC pharmacy services, whether provided and billed directly or through a subcontractor, at the rates established in DHCFP regulations at 114.3 CMR 31.00.

(130 CMR 405.467 through 405.470 Reserved)

405.471: Optional Reimbursable Services

A CHC may elect to provide the following services on site or by referral, but it is not required to do so under 130 CMR 405.000. The CHC must notify MassHealth in writing of each service listed in 130 CMR 405.471(A) through (F) that the CHC will provide on site. All services provided on site must be provided and payment claimed in compliance with the applicable MassHealth regulations for each service, including applicable fee schedules. Services the CHC may elect to provide include:

(A) adult day health services;

(B) adult foster care;

(C) day habilitation;

(D) family planning;

(E) psychiatric day treatment; and

(F) speech and hearing services as described in 130 CMR 413.000.

(130 CMR 405.472 through 405.495 Reserved)

405.496: Utilization Management Program

MassHealth pays for procedures and hospital stays that are subject to the Utilization Management Program only if the applicable requirements of the program as described in 130 CMR 450.207 through 450.211 are satisfied. Appendix E of the *Community Health Center Manual* contains the name, address, and telephone number of the contact organization for the screening program and describes the information that must be provided as part of the review process.

REGULATORY AUTHORITY

130 CMR 405.000: M.G.L. c. 118E, §§ 7 and 12.